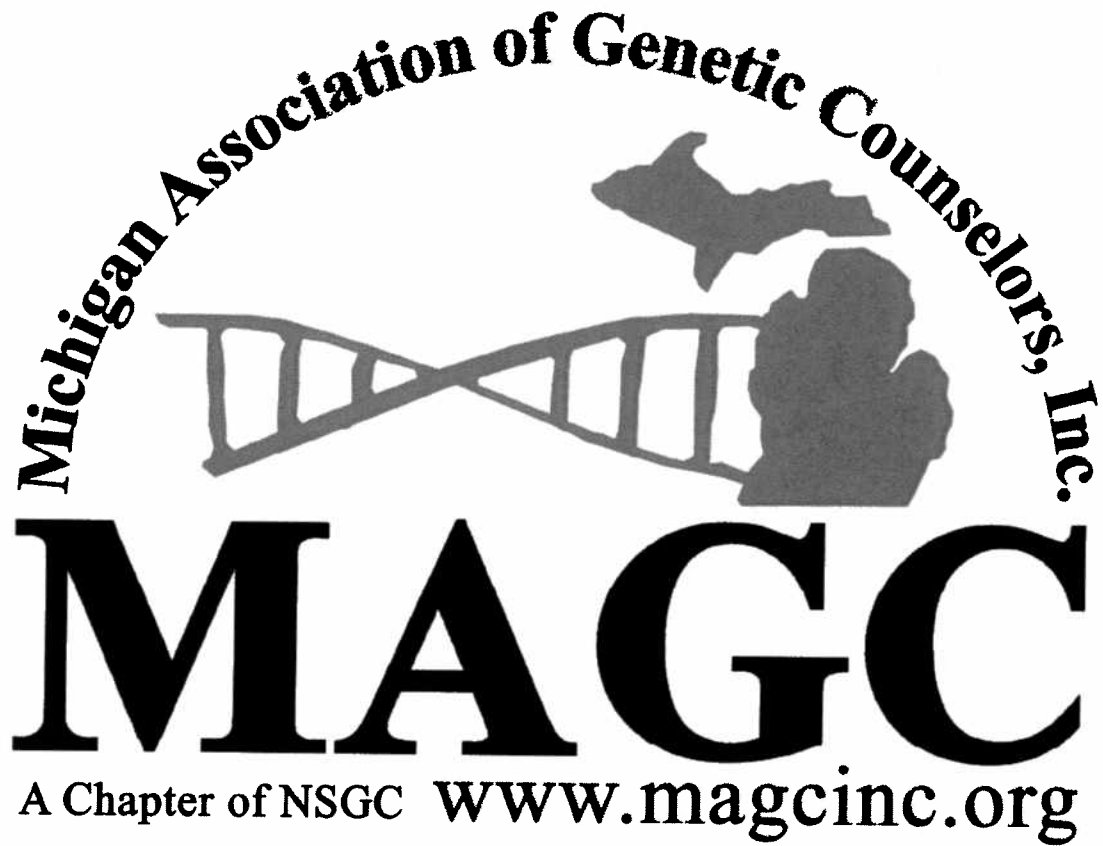


Licensure for Michigan Genetic Counselors

Prepared by



June 2011

Now is the Time to License Michigan Genetic Counselors

Genetic Counselor Licensure will provide Michigan citizens:

- **Protection from harm of receiving inaccurate information about genetic risks from individuals who do not meet minimum education and certification standards.**
 - Numerous cases of physical, psychological, or financial harm due to the inappropriate use or interpretation of genetic information in Michigan have been described.¹
 - Errors in care may be inevitable, but regulating providers through competency guidelines should reduce the frequency.
 - Approximately 30% of non-genetics health care providers misinterpret the results of genetic tests that they order on their patients.² These errors in interpretation can have a significant impact on patients and their family members.
- **Cost savings of healthcare dollars via accurate testing on appropriate individuals.**
 - Healthcare providers without training in genetics often order more expensive genetic testing than is indicated, amounting to unnecessary health care expenditures.³
- **Assurance that minimum education, continuing education, and certification standards have been met by individuals using the title of genetic counselor.**
 - Genetic counselors hold advanced degrees and are uniquely trained to provide their services.
 - The public and some healthcare providers are generally unaware of the minimal standards for formally trained genetic counselors. In fact, patients report receiving services from what they originally believed to be genetics experts, when in fact the providers of these services had very limited, if any, formal genetics training.
 - The growing availability of direct-to-consumer genetic testing makes the urgency of ensuring the availability and recognition of quality genetic counseling services to patients in Michigan even greater.⁴
 - Human genetics is advancing rapidly, making continuing education critical. In 2011, genetic testing was available for approximately 2,058 diseases, an increase of over 1,000 diseases over the last 10 years. In the absence of regulation, compliance for important continuing education may be deficient since adherence to professional recommendations is otherwise voluntary and not required to work as a genetic counselor.
- **Reassurance that the quality of care in the state of Michigan is comparable to that of neighboring states.**
 - Some of our nearest neighbors, Illinois and Indiana, have enacted laws for genetic counseling licensure. Ohio and Wisconsin are actively pursuing similar legislation.
 - Without licensure, individuals without the appropriate credentials could provide genetic counseling and therefore decrease the quality of the service in Michigan as compared to neighboring states with regulation.
- **A mechanism to report, investigate, and sanction claims of incompetent, unethical, and/or unlawful behavior of a genetic counselor.**
 - In the absence of regulation, there are no professional consequences for practicing outside of defined guidelines. Without regulation, incompetent genetic counselors can continue practicing, leaving families in Michigan vulnerable.
- **Guarantee that the state is working to train and retain highly educated health care professionals.**
 - The state of Michigan is home to two graduate training programs in genetic counseling. Graduates of these programs are in high demand and consider the availability of licensure in a state when seeking employment.

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3. Plon SE, et al. Genetic testing and cancer risk management recommendations by physicians for at-risk relatives. *Genet Med*. 2011;13(2):148-54.
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***Genetic counselors are the health professionals specifically trained to address
the complex issues associated with genetic disease.***

"Genetic counseling is a critically important component of the appropriate use and integration of genetic tests and services"

Report of the Secretary's Advisory Committee on Genetics, Health, and Society. 2006



Genetic Counselors

Uniquely qualified and solely dedicated to providing competent genetic counseling services¹

Genetic
counseling is
the process of
helping people
understand
and adapt to
the medical,
psychological,
and familial
implications of
genetic
contributions
to disease.²

Genetic counselors are health care providers uniquely trained in Master's degree programs to provide quality genetic-based services. Genetic counselors are certified by the American Board of Genetic Counseling. Genetic counselors work in diverse health care settings in Michigan, including universities, industry, public and private health care settings. Areas of practice include: pediatrics, cancer, neurogenetics, reproductive, and other specialty genetics clinics.

In health care settings, genetic counselors are responsible for:

- Eliciting and interpreting medical and family histories.
- Calculating the risk of occurrence or recurrence of a genetic condition.
- Imparting clear, accurate and comprehensive information regarding medical conditions with a genetic component to patients and healthcare providers; including risks, symptoms, screening and treatment options as well as testing options.
- Providing psychosocial support to individuals and families coping with a genetic condition.

Genetic counselors work closely with individuals and families to:

- Evaluate the appropriateness of pursuing genetic technologies.
- Facilitate informed decision-making.
- Communicate with the family, laboratories and other healthcare providers.
- Promote screening and preventative care to minimize health risks.

Genetic counselors:

- Recognize and respond to ethical and moral dilemmas related to genetic disorders.
- Identify factors that promote or hinder client autonomy with genetic services.
- Understand issues surrounding privacy, informed consent, confidentiality, and real or potential discrimination.

To find a genetic counselor, go to
www.nsgc.org or www.abgc.net.

To view the centers where genetic
counselors work, visit
www.migeneticsconnection.org.

Each year, thousands of Michigan residents benefit from the services provided by genetic counselors.

- 1 in every 20 babies is born with a birth defect³
- 20-30% of all infant deaths are due to genetic disorders⁴
- 1 in every 9 pediatric hospital admissions is for a child with a genetic disorder⁵
- 1 in every 8 adult hospital admissions is for a genetic cause⁶
- 50% of mental retardation has a genetic basis⁷
- 15% of all cancer has an inherited susceptibility⁸
- 10% of chronic disease (heart, diabetes, arthritis) has a significant genetic component⁹

Michigan: Historically at the Forefront in Genetic Matters

Michigan government has proudly been at the forefront in passing legislation regarding matters related to genetics that affect the state's citizens. These laws and policies have aided in the protection of genetic information and appropriate use of quickly advancing genetic technology. Various examples of such laws and policies can be reviewed at <http://www.migeneticsconnection.org/policy.shtml>.

These laws and policies that have addressed such matters as identification of infants with genetic disease, employment discrimination due to genetic information, health insurance protection in light of genetic test results, and informed consent have addressed burgeoning issues that confront our families. Michigan's citizens have benefited from the legislation that has been passed. Now it is time to protect their clinical care by licensing genetic counselors, those health professionals specifically trained to address the complex issues associated with genetic disease. Please refer to "Points to Consider: Licensure for Genetic Counselors in Michigan" for further details on how this legislation would protect the citizens of Michigan. Further information about genetic counselors in Michigan can be found in the Genetic Counselor Fact Sheet and at the website of the Michigan Association of Genetic Counselors, www.magcinc.org

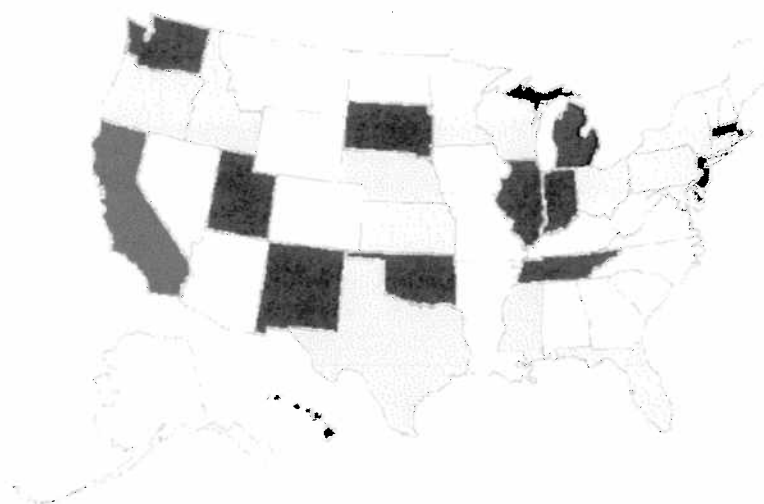


FIGURE 1: States with legislation for licensing genetic counselors

LEGEND	
	-- States Issuing Genetic Counseling License
	-- States with Licensure Law, but Rulemaking
	-- States with Licensure Bill Introduced
	-- Michigan introduced bill in House Committee in 2010; currently re-introducing to House Committee

Michigan's proud tradition of leading in genetic legislation is in jeopardy as more and more states license their genetic counselors. Currently, there are 13 states that have passed legislation for licensing genetic counselors. What is more, some of Michigan's nearest neighbors, Illinois and Indiana, have enacted laws for genetic counseling licensure, while Wisconsin and Ohio are actively pursuing bills. This movement has set a standard for our region and Michigan should lead the way rather than lag behind.



*The leading advocate for quality genetic
counseling services in the State of Michigan*



House Bill _____

Licensure of Genetic Counselors

Genetic
counseling is
the process of
helping people
understand
and adapt to
the medical,
psychological,
and familial
implications of
genetic
contributions
to disease. ²

Genetic Counselor Licensure will provide Michigan citizens:

- Assurance that individuals using the title genetic counselor have attained minimum education and certification standards.
- Reduction in the likelihood of causing harm by receiving inaccurate information about genetic risks from individuals who do not meet these minimum education and certification standards.³
- Increased access and lower costs to consumers for genetic services.^{1,4}
- Assurance that genetic counselors maintain a minimum level of continuing education.
- A mechanism by which claims of incompetent, unethical, unlawful behavior of a genetic counselor can be reported and investigated as well as provide a means to sanction a genetic counselor for proven offenses of these claims and/or for operating outside of their scope of practice.

June 23, 2011 House Health Policy Committee Testimony:

- Testimony will be provided at this Committee meeting on the Genetic Counselor Licensure Bill, sponsored by Representative Mike Callton.
- We hope that when the Bill comes out of Committee you will be supportive when it is in front of the full House.
- Our Licensure bill from 2010 was successful in coming out of the House Health Policy Committee.

Please contact Whitney Ducaine, MGC, CGC, for more information about this Bill: 248-551-3378 or whitney.ducaine@beaumont-hospitals.com. Whitney is a certified genetic counselor and the MAGC Professional Development Chair.

Licensure for Genetic Counselors in the State of Michigan

Cases of Harm

The cases below illustrate instances where health care providers gave individuals erroneous information regarding genetic conditions and/or testing. Patients often believe they are seeing a “genetic counselor” when a health care provider gives them genetic information and orders genetic testing. Licensure for genetic counselors would seek to limit who can use the title “genetic counselor” and would therefore ensure that patients are provided with appropriate information. Unfortunately, the patients in these cases made decisions based upon the misinformation given, sometimes resulting in poor outcomes. The identities of the patients, health care providers and institutions are not provided due to issues of confidentiality.

Selected Cases of Harm in Michigan

1. February 2011 – Royal Oak (Oakland County) A 42-year old woman was self-referred for post-test genetic counseling after receiving positive *BRCA2* test results through a Direct-To-Consumer (DTC) testing company. She had received a coupon for a discounted cost of genetic screening test that would "Gain insight into your traits, from baldness to muscle performance. Discover risk factors for 97 diseases. Know your predicted response to drugs, from blood thinners to coffee." (www.23andme.com). She elected to pursue the test, since she thought it could help her live a healthier lifestyle. She received her test results online, and was so shocked by her *BRCA2* positive results, she did not know what to do or how to further understand these results. She was "freaking out" from this result. She had not told her husband or support system about the testing, and had no idea how to bring her results up with them. She googled "genetic counselors" in Michigan, and found a local cancer genetic counselor. She was seen the next day in clinic and was found to have extreme psychological stress and fear from the test result. Her counselor was able to help her understand the implications of her results, and how to cope with the information. She has seen her genetic counselor four times over several months and is finally able to accept her *BRCA2* positive status as beneficial to her and not harmful.

2. January 2007 -- Royal Oak (Oakland County) A 49-year old breast cancer survivor was referred for genetic counseling and testing by her oncologist because she had developed breast cancer at age 42. The patient met with a genetic counselor and understood the implications of testing *BRCA+* and indicated that she would elect to have a prophylactic bilateral mastectomy and oophorectomy if she carried a mutation. The patient's insurance, however, required her to be seen at another facility for testing where she was seen by a nurse who had been trained by the laboratory with the patent for *BRCA1/2* testing. The patient was offered testing at this facility, tested *BRCA* negative, and a copy of her test results were sent to her in the mail. The patient was relieved for herself and her family members, and continued regular breast surveillance. Four months later the patient faxed her oncologist and genetic counselor a copy of her test results. Her genetic counselor noticed that she had been tested for the three common Jewish *BRCA*

mutations; however, this patient was not of Jewish ancestry. The wrong test had been ordered. Full sequencing of *BRCA1* and *BRCA2* was then ordered and the patient tested positive for a *BRCA2* mutation. The patient went on to have a prophylactic bilateral mastectomy and total abdominal hysterectomy and her family members learned that they were in fact at risk for this familial *BRCA2* mutation. Had a genetic counselor not reviewed the report and noted the error, the patient and her family would have had a false sense of security and would like have not been aware of the risk reducing interventions available.

3. 2003 Grand Rapids (Kent County) A 12 year old boy was diagnosed with metastatic colorectal cancer. During his hospitalization, a genetics consult was requested due to his family history of familial adenomatous polyposis (FAP), an autosomal dominant condition. When the genetic counselor and geneticist met with the patient and his mother, they learned that his mother had been diagnosed with FAP and had undergone a colectomy in her late teen years. The mother stated that she was UNAWARE of the 50% risk for each of her children to inherit FAP and that screening for children with FAP typically begins with sigmoidoscopy or colonoscopy in childhood (by the age of 12). The mother's lack of understanding regarding the genetic basis of her disease meant that her son did not receive the appropriate screening. The patient died of his cancer within the following year.

4. October 2009–Royal Oak (Oakland County) Patient referred for prenatal genetic counseling regarding a family history of Fragile X syndrome (FXS). The referring physician forwarded copies of previous genetic testing for FXS performed on the patient and her then fetus for FXS, which showed normal results in both patient and her fetus. In reviewing the family history, the patient's sister is known to have FXS, which makes this patient's risk for being a FXS carrier 50%. However, her previous carrier test result indicates that she was found to not be a FXS carrier and, therefore, not at risk for having a child with FXS. When this information and report were presented to this patient, she indicated that she had never been told she had carrier testing done or that the result had given negative results. She soon realized that the prenatal testing she had done in previous pregnancies had, in retrospect, not been warranted and that prenatal testing in this pregnancy was not warranted, either and subsequently cancelled the appointment for amniocentesis she had scheduled for later that day. She and her husband asked several times why had they had not been informed of her test results once they were known. They were referred back to her physician to have this explained to them. Although the referring physician had recognized that the patient was at higher risk for having a child with FXS based on her family history, he did not recognize or order carrier testing for her prior to offering and performing genetic testing on her fetus. Upon review of the records, the patient's carrier testing was done as a reflex test by the genetics laboratory performing the fetal testing which is routine whenever a prenatal sample is ordered; if this had not been initiated by the genetics laboratory, this patient would likely have never been offered this testing and would have continued to believe she was at increased risk for having a child w/FXS when she, in actuality, had no higher risk at all. The patient could have avoided the invasive prenatal testing procedure performed in the previous pregnancies, which is associated with a risk for miscarriage.

5. September 2009-Grand Rapids (Kent County) 50 year old female tested for *MLH1*, *MLH2*, and *MSH6* by her OB/GYN without any prior counseling. Patient had endometrial (uterine) carcinoma *in situ* diagnosed at 34 years (no attempt at MSI/IHC), her father had colon cancer at age 65-70 and had colon polyps, paternal grandfather with colon cancer and polyps (age unknown). Patient tested positive for a deleterious mutation in *MLH1* and was then referred to genetic counseling. When talking to her over the phone, it became clear that she had never heard of HNPCC before, did not know what she had tested positive for, had no idea what cancers she was at risk for, that it could be passed on. By the end of our conversation she said “her head was spinning” with all the information as she had never heard any of this before. She was also unaware that she needed a colonoscopy. Had the patient seen a genetic counselor prior to testing, money would have been saved through MSI/IHC testing prior to germline mutation testing and the patient would have understood the condition and implication of the diagnosis (test results). Informed consent was not performed, which is state law in Michigan, since this patient had no idea what she was being tested for, let alone her results.

6. June 2009-Grand Rapids (Kent County) Patient was diagnosed with rectal cancer at age 29. Family history is strongly suggestive of HNPCC (hereditary non-polyposis colorectal cancer). Non-genetics physician ordered immunohistochemistry testing on rectal cancer which showed loss of expression of *MSH2* and *MSH6*. The majority of the time this would indicate that there is a germline (i.e., inherited) mutation of *MSH2*. Subsequently, the non-genetics provider offered comprehensive Colaris testing through Myriad Genetics which tests for *MLH1*, *MSH2*, and *MSH6* genes when testing only for *MSH2* would have likely been necessary. Testing for only *MSH2* only versus testing all three genes would have saved \$1850.00.

7. March 2009-Royal Oak (Oakland County) 25 month old boy recently diagnosed with Fragile X syndrome (FXS), a genetic condition that causes developmental/learning problems/mental retardation. His mother reports that she first brought up concern for FXS at 18 months when the child was not meeting developmental milestones and brought up at that time that she has a family history of this condition as well. The pediatrician reassured her that the child was not that far off in development and thought they should wait before having any evaluations done. When the child began having social anxiety and hand-flapping at 20 months, she again brought concern for FXS up and pediatrician recommended developmental evaluation but not genetic testing. The developmental pediatrician agreed that there were developmental delays at 22 months, doubted he had FXS but indicated testing was appropriate only if the parents wanted to pursue it; again, they were told that the developmental problems (mainly speech and social anxiety) were not typical of FXS and doubted this diagnosis. The mother then researched FXS more thoroughly, learned that speech delay and social issues were very typical of FXS and she specifically requested the testing be ordered. The pediatrician then arranged for testing and the result confirmed that the child did in fact have FXS. The mother is very angry that she was repeatedly told not to worry about the family history and that his speech delay was not typical of FXS none of which is accurate. Also, she does plan on having more children and the delay in diagnosis may have resulted in her having another affected

child before learning of the diagnosis; she is in fact a carrier of FXS and her risk of having other affected children is in the range of 50%.

8. February 2009-Ann Arbor (Washtenaw County) A 46 year old woman unaffected woman with a family history of breast cancer in her mother, maternal grandmother, and paternal aunt contacted a genetics clinic about the following situation. She discussed this family history with her local physician who then offered her *BRCA1/2* testing which came back as “no mutation detected”. Based on this result, her physician told her that she was not at increased risk for cancer; she did not believe this to be correct; the physician then instructed her to contact the genetics clinic to clarify this further. Patient is correct, there are other genes which can increase someone’s risk for breast cancer other than *BRCA1/2*.

9. February 2009 - Farmington Hills/Royal Oak (Oakland County) An individual presented for genetic counseling after her blood was reportedly drawn for genetic testing of the *BRCA1* and 2 genes (breast/ovarian cancer 1 and 2 genes). The patient was counseled but did not receive informed consent prior to her blood draw. She was incorrectly informed how quickly her results would become available (she was told less than 1 week). She was recently diagnosed with breast cancer and these results were going to help her decide between a lumpectomy or mastectomy (unilateral vs. bilateral). Patient signed a medical record release form for the genetic counselor to obtain her results when available. When contacting the laboratory, we were told that a blood sample had never been received on this patient and did not have any record of this patient at all. Upon following up with the referring physician’s office, the nurse who had drawn the patient’s blood actually ordered *BCR-abl* genetic testing (this is associated with chronic myelogenous leukemia, NOT breast cancer). The patient did receive these results in less than 1 week and was informed that she was negative but this was for the wrong gene. The patient was contacted by a genetic counselor to tell her about this situation and was scheduled for an appointment in the genetics clinic to have her blood drawn for the correct test. The patient will not have these results in time for her surgery and will have to make her surgical decision without the results. If the patient had been referred for genetic counseling PRIOR to her initial blood draw, the appropriate test would have been ordered, she would have had results prior to her surgery, she would have been properly informed and consented per Michigan law, and the patient would not have been informed inappropriately of her results being negative.

10. February 2009 – Flint (Genesee) The parent of a patient with Fragile X syndrome (FXS) contacted a genetics program regarding genetic testing that was performed on their 9 year old daughter who is healthy and developmentally normal. The parent reported that one of her son’s specialists recommended their daughter have carrier testing for FXS “anytime” and, subsequently, they had the testing ordered by the child’s primary care physician. The test report faxed to our office and upon our review we learned that the test order was for a routine chromosome analysis rather than a molecular FXS test. This result showed a “marker chromosome”, that is, a small extra bit of chromosome material that is not able to be further characterized without further study. The meaning of this result is very dependent upon the reason for ordering the study – if a child is having

developmental and/or medical difficulties it is probably a significant result but in an otherwise healthy child, its significance is probably very minimal. A number of harms occurred here. First, it is not recommended that healthy minors have genetic testing for genetic disorders for the sole purpose of determining that child's future reproductive risks as the child should have the opportunity to decide for himself/herself at the appropriate age and time for which they can make independent decisions. Second, an incorrect test was ordered simply because the ordering provider did not know that chromosome analysis is not the test to order for FXS; a genetics professional would have known this and ordered the appropriate test. Now, the family is confronting results on a healthy child that will likely have little impact on her medical care but still raises questions that did not need to be raised at all. Additionally, a routine chromosome analysis is about twice the cost of a FXS test so an inappropriate, more costly test was done.

11. October 2008 – Ann Arbor (Washtenaw County) A 45 year old woman presented for a second opinion regarding her *BRCA1* genetic test results. Her mother, who had breast and ovarian cancer) was tested first and was found to have a known deleterious mutation in *BRCA1* with a *BRCA* VUS (“variation of unknown significance”). This patient was then tested through her primary care physician and found not to have the deleterious mutation but did have the VUS. The VUS is a polymorphism (“normal variation”). The patient was shocked when we told her this was a true negative test result. The patient was under the impression from her primary care physician that this was a deleterious mutation and she would need to consider prophylactic mastectomy and oophorectomy. This patient could have potentially had life altering prophylactic surgery for a 10% lifetime risk for breast cancer and less than 1% lifetime risk for ovarian cancer.

12. September 2008 – Ann Arbor (Washtenaw County) a woman who has a known *BRCA2* mutation in her family was tested through her primary care physician's office. The primary care physician, instead of ordering the less expensive single site analysis, ordered complete gene sequencing of the *BRCA1* and 2 genes. Because the primary care physician did not know the appropriate test to order, the patient's health insurance company paid \$3120.00 for what should have been just a \$385 cost for the family mutation.

13. August 2008, West Bloomfield (Oakland County) 80 year old male presented to his PCP regarding a family history of *BRCA1* mutation recently identified in his sister. PCP informed patient that *BRCA1/2* testing is not useful in men/not covered by insurance and test costs over \$3000. The patient was determined enough to call and clarify this information with the genetics department. Patient was seen in our clinic, testing was paid for by his insurer, and he is positive for this mutation. Patient has four children (2 males; 2 females).

14. January 2008 (Oakland County) Infant girl who had been born prematurely (27 weeks gestation) and was still in intensive care in an Oakland County hospital genetics consultation was requested because of a recent diagnosis of Prader-Willi syndrome (PWS). This child had a prolonged course of low muscle tone and feeding difficulties. Prior to requesting genetic consultation, this patient's physicians had already ordered a

number of genetic tests, some which were very expensive and one of which involved doing a muscle biopsy. The last test done was for PWS, a condition that is known to be a common cause of low muscle tone and feeding difficulties in babies. This child's diagnosis was delayed unnecessarily as well as the treatment for it. This child had physical harm in having a muscle biopsy that was, in retrospect, unnecessary. The family suffered emotional distress from not being able to know the prognosis for their child earlier in the course of her hospitalization. Had the physician caring for this baby recognized the need for testing for PWS earlier, many of the tests done to determine the reason for the problems would not have been needed.

15. September 2007 (Oakland County) A 42 year old pregnant woman was seen for genetic counseling and was offered carrier testing for cystic fibrosis as this is standard of care. The patient discussed this testing with her primary care physician as well. She was informed by the nurse in the physician's office that carrier testing was not needed unless there was a family history of this condition. The patient called the genetic counselor to ask about this further. The genetic counselor appropriately informed this patient that, although people with a family history are at higher risk for being carriers, even those without a family history can be a carrier. In fact, approximately 4% of the general Caucasian population are carriers. The incorrect information provided by the nurse led to confusion about the need for testing and led to delays in getting this testing done.

16. October 2007 (Kalamazoo County) A pediatric patient was hospitalized with new onset seizures. She had been recently evaluated for the first time by the genetics clinic and a number of tests had been ordered. While in the hospital, test results for Rett syndrome were returned and revealed a genetic change in the gene associated with this condition, confirming that the patient had Rett syndrome. The genetic counselor had attempted to reach the family to inform them of this result but was unable to reach them because of the hospitalization. The hospital called the genetics clinic to obtain the results and these results were released as per protocol. The family later reported to the genetic counselor that a resident physician informed them of the results and told them that the patient had only 6 months to 2 years to live because of this diagnosis. The family suffered severe emotional upset due to this misinformation. The emotional distress was alleviated when the genetic counselor was able to talk to the family and provide reassurance regarding the prognosis as it relates to the expected lifespan.

17. August 2007 (Oakland County) a 14 year old girl with birth marks was seen by a nurse practitioner (NP) who works with a Family Practice physician in Oakland County. The NP appropriately considered the possibility of this patient having a genetic condition called neurofibromatosis (NF-1). The NP called the genetics clinic to inquire if the chromosome analysis that had been done and had given normal results was sufficient to "rule out" NF-1 for this patient. The NP spoke with a genetic counselor and was informed that a chromosome analysis is not an appropriate test for NF-1 and the normal result does not tell us anything about this condition. The NP was given the clinical criteria used to make this diagnosis and the name of the appropriate gene test as well as offering to see this patient in the genetics clinic. The harm incurred is that testing was done which was not appropriate and the appropriate evaluations had not been done.

18. April 2007 (Oakland County) A 4 year old girl was referred for genetic evaluation because of slow growth. In reviewing her history, a genetic condition called Prader-Willi syndrome (PWS) had been considered previously, genetic testing had been done which gave a normal result. The family was told that this girl did not have PWS. In reviewing the details of her case more thoroughly, it was learned that this child had many characteristics of PWS but that the testing her neurologist had ordered was an older genetic test for PWS that only gives abnormal results in 70% of people with PWS. A better test for PWS has been available since the mid 1990s that gives abnormal results in essentially all people with PWS; this testing was done and showed that this child did have PWS. This family was harmed by being given incorrect information about the child's condition, not having the appropriate diagnostic test done and undergoing a series of medical evaluations that, in retrospect, were unnecessary and expensive. Additionally, there is treatment for PWS that, had the correct diagnosis been made, could have been started much earlier.

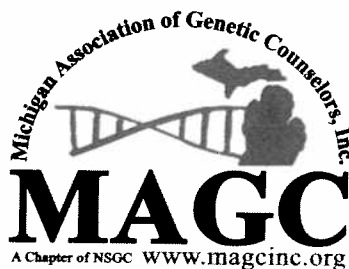
19. 2007 Grand Rapids (Kent County) A woman with breast cancer in her mid 20's requested a bilateral mastectomy due to her concerns about developing a second breast cancer. Her breast surgeon told her a bilateral mastectomy was not necessary and that a lumpectomy would be sufficient. A lumpectomy was performed. Following her lumpectomy, genetic testing for *BRCA1* and *BRCA2* was performed and revealed that the patient had a *BRCA1* mutation, placing her at a significantly increased risk for a contralateral breast cancer, and making a bilateral mastectomy a very reasonable option. The patient is now seeking a bilateral mastectomy. Had genetic testing been considered at the time of her initial diagnosis or at the time of her initial request for a bilateral mastectomy, the patient could have avoided an extra surgical procedure (the lumpectomy) by proceeding directly for the mastectomy.

20. November 2006 Grand Rapids (Kent County) A pregnant woman had an ultrasound revealing "soft signs" for Down syndrome in her fetus. She was told by her OB/GYN to have an amniocentesis, the results of which indicated a fetus with Trisomy 21 (Down syndrome). The OB/GYN, misreading the amniocentesis report also told the patient that the baby had spina bifida, and based on this information she decided to terminate the pregnancy. She was not seen by a genetic counselor at any time until she was fortunately scheduled her termination at a center requiring genetic counseling prior to this procedure if the indication was for fetal anomalies or genetic diagnosis. The genetic counselor correctly interpreted the amniocentesis results and counseled the woman that the fetus DID NOT have spina bifida or any other birth defect other than Down syndrome. Based on this information the patient chose to continue her pregnancy. She is still traumatized by what happened.

21. 2002 (Oakland County) A 30 year old with a family history of Fragile X syndrome (FXS) and who was a known FXS carrier had amniocentesis via her obstetrician in an Oakland County hospital. Results indicated that the baby was female and had inherited the genetic change, which causes FXS. The obstetrician counseled the family without referring the couple to a genetic counselor and informed the family that the child would

be a FXS carrier, but that girls usually do not have FXS itself. This information is incorrect. Although some girls with the gene change for FXS may not show signs of it, many do. At 3 years old, this girl was diagnosed with autism, which is a well known sign of FXS. However, the connection between her FXS test result and the autism was not made until her mother saw a genetic counselor for a different matter. The genetic counselor correctly informed the family that FXS commonly causes autism as well as other developmental problems; these problems can occur in both boys and girls with FXS. Because no one had informed the family of the relationship between the prenatal test result and developmental problems, they had not reported the prenatal result to her daughter's physicians. This led to this young girl having many attempts to find a reason for her difficulties while the answer was already available. In fact, the patient herself was cognitively impaired due to her own Fragile X diagnosis. This family went on to have another child that also had FXS because of failure to communicate appropriate information about the family history to healthcare providers. The primary event was the obstetrician failing to recognize that females with an abnormal FXS result can have significant problems from this. Had the obstetrician referred this patient for genetic counseling when this initial test result was known, accurate information regarding this diagnosis would have been given and the family would have realized that their daughter's autism was caused by this genetic change. It is likely that this girl would not have needed to undergo as many evaluations in an attempt to determine the reason for her difficulties. This entire family was harmed medically in that the daughter was not appropriately diagnosed and did not receive appropriate intervention at an earlier age.

22. October 2000/July 2006 (Mecosta County) 50 year old female underwent asymptomatic genetic testing for Huntington's disease (HD) ordered by her PCP secondary to a family history of HD. DNA analysis revealed repeat numbers of 42 and 15; PCP informed patient that based on "low number of repeats", it is unlikely she would ever develop symptoms of HD and/or only develop symptoms at a much older age. Therefore, patient was not correctly given diagnosis of HD until July 2006 when, in retrospect, she has displayed symptoms since her late 30's.



Supporters of Licensure for Michigan Genetic Counselors

Updated June 2011

The following individuals and organizations have provided the Michigan Association of Genetic Counselors (MAGC) with letters documenting their support for licensure of Michigan Genetic Counselors. Copies of the letters are available on request.

Organization and Institutions

Children's Hospital of Michigan Division of Metabolic and Genetic Disorders
 Children's Hospital of Michigan Division of Pediatric Neurology
 Facing Our Risk of Cancer Empowered (FORCE)
 Henry Ford Hospital Department of Medical Genetics
 March of Dimes Michigan Chapter
 Michigan Health and Hospital Association
 Michigan Osteopathic Association
 Michigan Section of the American College of Obstetricians and Gynecologists
 Michigan State Medical Society
 National Society of Genetic Counselors
 University of Michigan Medical School
 Wayne State University Genetic Counseling Program
 Wayne State University Department of Obstetrics and Gynecology
 Wayne State University School of Medicine
 William Beaumont Hospital

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